

K090633

Premarket Notification 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

Applicant: LensAR, Inc.
250 South Park Avenue, Suite 310
Winter Park, FL 32789 MAY 13 2010

Contact Person: Keith Edwards
Director, Clinical/Regulatory Affairs
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Date Summary Prepared: November 16, 2009

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

Trade/Proprietary Name:	TBD
Common/Usual Name:	LensAR Laser System for Anterior Capsulotomy
Device Classification:	<ul style="list-style-type: none">• Nd:YAG Laser for Posterior Capsulotomy and Peripheral Iridotomy, Class II, 21 CFR 886.4392• Radiofrequency Electrosurgical Cautery Apparatus, Class II, 21 CFR 886.4100• Ophthalmic Femtosecond Laser, Class II, 21 CFR 886.4390
Product Code(s):	NCR, LXS, OOE

PREDICATE DEVICES:

510(K) Number	TRADE NAME	MANUFACTURER
K892058	ISL QC 2000	Intelligent Surgical Lasers
K001498	The Fugo Blade	Medisurg Research and Management Corp.
K082947	LenSx	LenSx Lasers, Inc. 33 Journey, Suite 175 Aliso Viejo, CA 92656
And by LenSx reference the following devices:		
K033354	FEMTEC Laser Microkeratome	20/10 Perfect Vision Optische Gerat GMBH
K993153, K001211, K002890, K013941, K031960, K041893, K060372, K063682, and K073404	IntraLase FS Lasers	IntraLase Corp.

DEVICE DESCRIPTION:

The LensAR Laser System is an ophthalmic surgical laser intended for use in anterior capsulotomy in cataract surgery. The System employs a mode-locked Nd:YVO₄ laser which generates a high frequency series of ultrashort, low energy pulses at a wavelength of 1064 nm. The system is designed to cut the lens capsular tissue, with minimal collateral damage, by the mechanisms of plasma mediated ablation and photodisruption of targeted tissue at the beam focus. The precision capsulotomy is generated by computer-controlled scanning of the position of the laser beam focus in three dimensions at the target location of the anterior capsulotomy. The laser energy is delivered to the eye through a disposable, patient interface device consisting of an Index Matched Eye Docking device (IMED) designed to match the refractive index of the cornea to optimize beam targeting accuracy. The IMED device is docked to the eye via an accessory component comparable to those used with other ophthalmic lasers used as keratomes.

INDICATIONS FOR USE:

The LensAR Laser System is intended for use in anterior capsulotomy during cataract surgery.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

As with the other ultrashort pulse lasers, the LensAR uses a mode-locked lasing technology rather than the Q-switched technology used for nanosecond or longer pulse lasers. The ultrashort pulses ionize target tissue molecules, creating free electrons through

a multi-photon absorption process rather than thermionic emission, the prevalent mechanism for somewhat longer pulse lasers. The electron avalanche and optical breakdown initiated by the free electron generation causes plasma formation and plasma mediated ablation as one of the cutting mechanisms.

The LensAR laser, like the LenSx, ISL QC 2000, Intralase (and others such as the FemTec laser), has laser beam and optical delivery system characteristics designed to generate a beam fluence at the beam waist that is enough above the laser induced optical breakdown (LIOB) threshold that the mechanical effects of shock waves and cavitation bubbles which are caused by the rapid plasma expansion constitute a substantial portion of the overall cutting process. The cutting of tissue by lasers via the aforementioned mechanical forces is termed photodisruption. The combination of substantial contributions to the cutting phenomenon from both plasma mediated ablation and photodisruption, as with the LensAR and other ultrashort pulse ophthalmic lasers cited above contrasts with the primarily laser mediated ablation mechanism utilized by ultrashort pulse lasers operating just above the LIOB or primarily photodisruption utilized by longer pulse Q-switched lasers.

Finally, like the other ultrashort pulse predicate devices, the LensAR laser uses a series of high frequency pulses which are scanned in three dimensions through the target tissue, by a computer-controlled optical scanning system, to create a contiguous cut. The ability to create a contiguous cut depends on matching the pulse-to-pulse spacings in three dimensions, to the three dimensional spatial extent of the plasma mediated ablation and photodisruption for the particular laser pulse width, pulse energy and optical delivery system characteristics.

The laser photodisruption plasma and the subsequent gas bubble are much smaller and more precise than an RF excited filament can achieve. If the focal spot is moved through the tissue in the appropriate pattern, macroscopic cuts can be performed that mimic those achieved with the Fugo Blade in the device-assisted anterior capsulotomy procedure in quality, but are much more controllable and repeatable in their key parameters since the cut is completely computer-controlled.

The LensAR Laser is, therefore, substantially equivalent to these legally marketed predicate devices.

BRIEF SUMMARY OF NON-CLINICAL TESTS AND RESULTS:

LensAR has developed the LensAR Laser for use in anterior capsulotomy, employing the precision and control of ultrashort pulse lasers for this procedure. Pre-clinical and clinical testing has included bench testing and a prospective, single-center, multiple surgeon clinical trial.

Summary of Pre-Clinical Testing

Testing and analyses performed included accuracy and reproducibility of capsulotomy size and depth in porcine eyes and plastic substrates. The data demonstrated the LensAR produces anterior capsulotomies that are uniform, accurate and predictable in size.

Additional safety testing was provided that addressed the acoustic and thermal profile of the device. Evaluation on *ex vivo* porcine eyes confirmed the safety with respect to corneal endothelium.

Summary of Clinical Testing

A clinical trial of the LensAR Laser was conducted to evaluate the performance of this laser system in the creation of anterior capsulotomy during cataract/IOL surgery, followed by conventional cataract removal. A contralateral control population which underwent continuous curvilinear capsulorhexis (CCC) and conventional cataract removal served as the comparative control, although not all fellow eyes underwent cataract surgery in the context of the clinical study. Clinical analysis included the pointing accuracy of the device, as well as the performance characteristics required to achieve an effective anterior capsulotomy cut.

Anterior capsulotomy was successfully performed in eyes using the LensAR Laser, with intraocular lenses successfully placed. Postoperatively, the course of follow-up through 3 months in the study population was unremarkable. The intraocular lens was centered in all study eyes. All capsulotomies were judged to be well centered by the surgeon using visual inspection in the operating microscope.

The ease of removal of the capsules was judged (on a scale of 1 to 10), with 1 being assigned as the score for Continuous Curvilinear Capsulorhexis (i.e., manual removal) and 10 being easiest to remove. All scores were 5 or better with the most common score being 10.

The removed anterior capsules from the laser treated eyes were demonstrated to be equivalent or better with respect to dimension and conformance to circularity than those done manually.

No significant difference in clinical outcomes from the sequelae of cataract surgery was demonstrated between the Treatment and Treated Control populations.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

LensAR, Inc.
c/o Ms. Shirley McGarvey
Consultant to LensAR
250 South Park Avenue
Winter Park, FL 32789

MAY 13 2010

Re: K090633

Trade Name: LensAR Laser System for Anterior Capsulotomy
Regulation Number: 21 CFR 886.4392
Regulation Name: Nd:YAG laser for posterior capsulotomy and peripheral iridotomy
Regulatory Class: Class II
Product Code: OOE
Dated: April 22, 2010
Received: April 23, 2010

Dear Ms. McGarvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

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and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

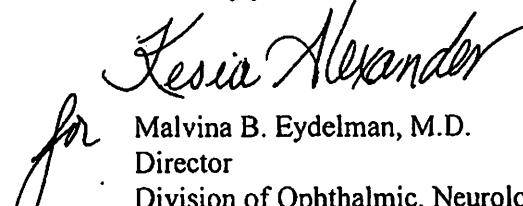
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for
Kesia Alexander

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Section 5: Indications for Use Statement

Indications for Use Statement

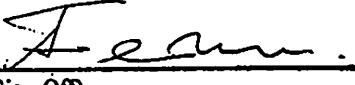
510(k) Number (if known): K090633

Device Name: LensAR Laser System for Anterior Capsulotomy

Indications for Use: The LensAR Laser System is indicated for anterior capsulotomy in cataract surgery.

Prescription Use: X **And/Or** **Over-the-Counter Use:** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)


Sean
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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